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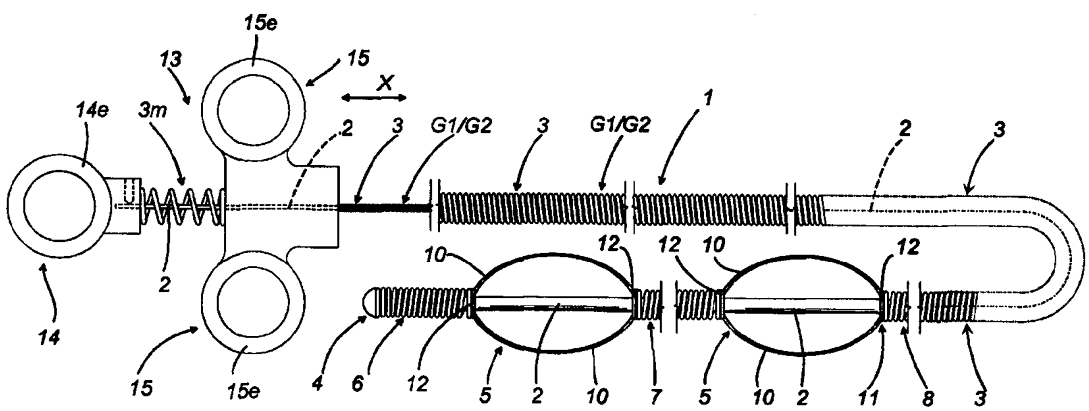
(54) Title: DEVICE AND METHOD FOR EFFECTING AN ANCHORAGE WHEN IMPLANTING BIFURCATED STENTS



(57) Abstract

A device designed to facilitate the operation of implanting an endovascular stent (201) in a vessel or passage (203, 203c) of the human or animal body employs at least one guide wire (G1, G2) consisting of a linear core (2) associated coaxially with a tubular sheath (3); the sheath (3) is secured to the core (2) at one end (4) and affords at least one weakened lateral area (5) designed to flex and enlarge elastically when subjected to the action produced by a relative axial movement between the core (2) and the sheath (3), in such a way as to expand beyond the normal width of the sheath (3) and engage the wall of the passage (203, 203c), remaining anchored until released by reversing the relative axial movement.

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DESCRIPTION

DEVICE AND A METHOD FOR EFFECTING AN ANCHORAGE WHEN IMPLANTING BIFURCATED STENTS

Technical Field

The present invention relates to a device by means of which to effect an anchorage when implanting a bifurcated stent in a passage of the human or the animal body, and to a method in which use is made of such a device.

Background of the Invention

Endovascular prostheses, referred to commonly as stents by persons skilled in the pertinent art or conversant with their use, are devices that can be implanted stably in a passage of the human or the animal body, typically a blood vessel or a natural duct that has become restricted as the result of a pathological or traumatic episode, to the end of inducing and maintaining patency and thus restoring normal function. The present invention relates more particularly to a device such as will facilitate the implantation of a so-called bifurcated type of stent, that is to say a stent designed to occupy a vessel exhibiting a main passage and a collateral passage. The prior art embraces a bifurcated endovascular stent and a relative method for its implantation, as disclosed in Italian patent application BO96A 000294 in the name of the same applicant.

Stents of the type in question are implanted with the aid of special guide wires each comprising a linear core accommodated coaxially within a tubular sheath, which is slidable in relation to the core. The insertion of the guide wires into the branched vessel allows a catheter to be directed into and along the main and collateral passages, which in turn enables the component parts of the bifurcated stent to be implanted in succession by guiding the catheter through a set sequence of steps. Whilst the results of clinical trials conducted using these same stents and the relative method of implantation have been entirely satisfactory, there are

nonetheless certain clinical cases, typified most notably by vessels exhibiting a severe and/or irregular stenosis, where the correct positioning of the stent, in particular as regards ensuring proper alignment between the ostium of a collateral passage and the gap afforded in the side wall of the component stent implanted in the main passage, is influenced both by the morphology of the vessel and by slippage attributable to torsional friction generated between the catheter and the guide wire during the actual alignment steps.

Disclosure of the Invention

Accordingly, the object of the present invention is to overcome the drawbacks in question by providing a device capable of anchoring itself firmly to the wall of the vessel, in the main passage or in the collateral passage as appropriate, and at the same time of aligning itself automatically relative to the wall in an operating configuration that has the effect of immobilizing the guide wire for as long as necessary during implantation.

The stated object is realized in a device according to the invention, as recited in the preamble of claim 1, wherein the linear core and the tubular sheath of the guide wire are secured one to another at one end and the sheath affords a lateral area weakened in such way as to respond to the action that accompanies a relative axial movement of the core and the sheath by deforming elastically to the point ultimately of interfering with the wall of the vessel and becoming anchored thereto.

A device embodied in accordance with the invention affords a number of advantages. A first advantage, deriving from the facility of anchoring the guide wire to the vessel wall, is that the surgeon can keep the wire taut in relation to the vessel during the subsequent positioning movements, and moreover, the catheter can be rotated as it is advanced along the wire without the risk of drawing the wire into rotation and losing the predetermined and correct position of the implant. This advantageous feature is the more significant particularly in the case of guide wires inserted into the collateral passage, which being necessarily of modest diameter are more susceptible than others to torsional interference and loss of initial position, whether occasioned by the catheter or by myoelectrical activity of the human or animal body during implantation.

A correctly and stably positioned guide wire also reduces the risk of the implant operation being prolonged by unforeseen events connected with the possible need to restore correct position if lost for whatever reason during one or other step of the procedure, thus ensuring that normal operating time schedules can be maintained even in the presence of somewhat complex clinical situations.

The advantages thus outlined are realized according to the invention in a method involving the use of the device disclosed to facilitate the implantation of a bifurcated endovascular stent comprising two component parts in a vessel of the human or animal body exhibiting a main passage and a collateral passage, to the end of bringing about its dilation. In particular, such a method comprises a succession of steps as recited in the preamble of claim 12, and incorporates the step of inducing a relative axial sliding movement in the core and the sheath of at least one guide wire such as will cause the weakened lateral area of the sheath to expand in a direction transverse to the core and to interfere ultimately with the wall of the corresponding passage, with the result that the guide wire as a whole remains anchored thereto. More exactly, the step of inducing relative axial movement precedes the step of advancing the catheter along the guide wire and into the relative passage.

Description of the Drawings

The invention will now be described in detail, by way of example, with the aid of the accompanying drawings, in which:

- figs 1 and 2 are two overall views of a device according to the present invention, illustrated in two typical operating configurations and enlarged appreciably;
- fig 1a shows a detail of the device as illustrated in fig 1, further enlarged;
- fig 3 shows a guide wire according to the present invention inserted into a passage of the human or animal body;
- figs 4a, 4b, 4b', 4c, 4d, 4e, 4f, 4g are schematic diagrams indicating a sequence of steps in a method of implanting an endovascular stent, wherein use is made of the device illustrated in figs 1 to 3;
- fig 5 is the overall perspective of a conventional catheter utilized for implanting an endovascular stent in a passage of the human or animal body.

Description of the Illustrative Embodiment

With reference to figs 1 and 2 of the accompanying drawings, 1 denotes a device, in its entirety, for use by surgeons when implanting an endovascular stent 201 in a vessel of the human or animal body comprising a main passage 203, and a collateral passage 203c branched from the main passage.

The device 1 comprises a guide wire G1 (and G2) composed of a linear core 2, consisting in a thin elastically compliant wire, and a tubular sheath 3 associated coaxially with the core 2. The core 2 and the sheath 3 are secured together at one end 4 of the device.

The sheath 3 takes the form preferably of a long, continuous and elastic spiral wound wire encircling the central core 2, and is also divided into two or more portions 6, 7 and 8 interconnected by tubular sleeves 5.

Each of the sleeves 5 illustrated can be considered as a cylindrical solid disposed with its peripheral surface coaxial to the core 2 and connected to two contiguous portions 6, 7 and 7, 8 of the sheath 3. The single sleeve 5 is embodied in such a way as to fashion the sheath 3 with a lateral area affording less resistance than the portions 6, 7 and 8 on either side when subjected to compressive forces acting on the sheath 3 in a direction parallel to the core 2.

A preferred embodiment of the sleeve 5, shown to advantage in fig 1a, comprises two rigid rings 12 and three elongated struts 10 (which could also be reduced to just two and remain equally functional), extending parallel with the core 2, of which the ends 11 are fixed to the rings 12 and equispaced around the core 2. The struts 10 combine notionally to envelop a lateral surface of the sleeve 5 that remains within the transverse dimensional compass of the sheath 3 and exhibits no discernible break in continuity with the portions of the sheath on either side.

In terms of mechanical strength, on the other hand, the lateral surface of the sleeve 5 behaves quite dissimilarly to the remaining portions 6, 7 and 8 of the sheath 3 when under compressive stresses applied to the sheath 3 in a direction parallel to the core 2. More exactly, the lateral surface of the sleeve 5 remains in alignment with the lateral surfaces afforded by the contiguous portions 6, 7 and 8 of the sheath 3 when not subject to such stresses, and thus within the dimensional compass of the sheath overall, whereas when compressed axially, the same lateral

surface of the sleeve 5 deforms elastically and expands transversely to the core 2, as indicated in fig 2, swelling beyond the transverse dimensional compass of the sheath 3.

It will be readily appreciated from the foregoing that the sleeve 5 might exhibit numerous different types of structure, all equivalent nonetheless from the functional standpoint. In effect, the elongated struts 10 could be fashioned as flat metal strips or thin flexible rods, or even as an elastically deformable membrane.

To advantage, the device 1 can be furnished with manipulation means denoted 13 in their entirety, consisting in rigid rods 14 and 15 associated respectively with the sheath 3 and with the core 2, of which the ends 14a and 15e are fashioned as rings for ease of handling. Such means 13 will be embodied separately from the device 1 in order to allow fitment of the relative component stent, as explained in due course, and attached to the device at a later stage utilizing conventional means not shown in the drawings. For the sake of simplicity in description and illustration, the means 13 in question are shown (figs 1 and 2) in an operating configuration assumed during implantation.

In operation, the rods 14 and 15 of the device 1 are displaced manually one in relation to another, between an at-rest condition and an operating condition, against the action of elastic means 3m consisting typically in an extension spring that might be embodied separately, as illustrated in figs 1 and 2, or alternatively embodied integrally with the sheath 3.

Given that the sheath 3 is subject substantially to the action of the return spring, as aforementioned, the spring tension existing between the core 2 and the sheath 3 will cause the device 1 to assume a position, when at rest (see fig 1), such that the lateral area of the sheath 3 coinciding with the sleeve or sleeves 5 remains within the transverse dimensional compass of the sheath 3 overall. In the operating configuration, conversely, with relative movement induced in the core 2 and sheath 3 by means of the rods 14 and 15 against the action of the return spring 3m, the lateral surface of the sleeve 5 is caused to deform and expand beyond the dimensional compass of the sheath 3.

The device 1 thus described allows advantageously of anchoring a guide wire G1 or G2 to the wall of a main passage 203, and/or to the wall of a relative collateral

passage 203c in the case of an implant involving the use of a bifurcated stent 201. In this instance, the general method of implanting a stent 201 of bifurcated embodiment, consisting effectively in two component stents 1P and 1S, is illustrated schematically in figs 4a, 4b, 4b', 4c, 4d, 4e, 4f and 4g. Such a method involves the use of a catheter 300 as illustrated in fig 5, which is comprehensively described and illustrated in the prior art reference mentioned above.

Referring to the drawings in question, the method of implanting a bifurcated stent will be seen to comprise the steps of:

- inserting a first guide wire G1 (fig 4a) through the main passage 203 and beyond the point at which the branch into the collateral passage 203c occurs;
- fitting a first component 1P of the bifurcated stent 201 together with expansion means 304 to a catheter 300 having two ducts 301 and 302 (fig 5), the component stent 1P exhibiting a configuration of minimum radial proportions and ensheathing the expansion means, which consist in practice of a balloon folded and arranged in such a manner as to leave one end 302e of the second duct 302 exposed;
- inserting the catheter 300 into the passage 203 and advancing it along the guide wire G1, which is inserted through the first duct 301, to the point at which the end 302e of the second duct 302 lies opposite the collateral passage 203c;
- inserting a second guide wire G2 (fig 4b) through the second duct 302 of the catheter 300 and into the collateral passage 203c;
- inducing relative movement between the core 2 and sheath 3 of the second guide wire G2 (as indicated by the arrow denoted x in fig 2), thus causing the weakened lateral area 5 of the sheath 3 to expand (fig 4b') transversely to the core 2 and interfere with the wall of the collateral passage 203c, with the result that the relative guide wire G2 remains stably anchored;
- operating the expansion means 304 in order to stabilize the first component stent 1P within the main passage 203 (fig 4b');
- withdrawing the catheter 300 from the passage 203 while the second guide wire G2 remains anchored in the collateral passage 203c;
- withdrawing the first guide wire G1 from the main passage 203;
- fitting the second component stent 1S to the catheter 300, in the configuration

of minimum radial proportions, then advancing the catheter 300 along the second guide wire G2 in such a way that the second component stent 1S is located in the collateral passage 203c (fig 4d) and brought to rest preceding the point at which the guide wire G2 is anchored in this same passage 203c;

- operating the expansion means 304 in order to stabilize the second component stent 1S within the collateral passage 203c (fig 4e);
- withdrawing the catheter 300 from the collateral passage 203c (fig 4f);
- releasing the manipulation means 14 and 15 and thus allowing the sheath 3 to shift in relation to the core 2 under the force of the return spring 3m, so that the guide wire G2 is no longer anchored to the wall of the collateral passage 203c;
- withdrawing the second guide wire G2 (fig 4g).

Claims

1) A device for effecting an anchorage when implanting an endovascular stent (201) in a passage (203, 203c) of the human or animal body, in particular a device (1) comprising at least one guide wire (G1, G2) composed of a linear core (2) and a tubular sheath (3) associated coaxially with the core (2), characterized

in that the sheath (3) is rigidly associated with the core (2) at one end (4) and affords at least one weakened lateral area (5) capable of deforming elastically in response to the action produced by a relative axial movement between the core (2) and the sheath (3).

2) A device as in claim 1, wherein the weakened area is incorporated as a tubular sleeve (5) located between and connected to two portions (6, 7; 7, 8) of the sheath (3).

3) A device as in claim 2, wherein the sleeve (5) is identifiable as a geometrical solid with a lateral surface disposed coaxial to the core (2).

4) A device as in claim 3, wherein the lateral surface of the sleeve (5) is membranous in embodiment.

5) A device as in claim 3 or claim 4, wherein the lateral surface of the sleeve (5) coincides with an envelope referrable to at least two elongated struts (10) supported by the sheath (3).

6) A device as in claim 3, wherein the lateral surface of the sleeve (5) coincides with an envelope referrable to at least three elongated struts (10) equispaced around the core (2) and with ends (11) connected to the two portions (6, 7; 7, 8) of the sheath (3) on either side of the sleeve.

7) A device as in claim 3, wherein the sleeve (5) comprises two rigid rings (12)

interconnecting the opposite endmost edges (11) of the lateral surface and connected to the two portions (6, 7; 7, 8) of the sheath (3) on either side of the sleeve.

8) A device as in claim 2, comprising elastic reaction means (3m) interposed and operating between the core (2) and the sheath (3), of which the function is to maintain the sheath (3) in a predetermined axial position relative to the core (2) when at rest.

9) A device as in claim 8, comprising elastic reaction means incorporated directly into the sheath (3).

10) A device as in claim 1, comprising means (13, 14, 15) by which to handle and manipulate the sheath (3) and the core (2), operated selectively in such a way as to occasion the relative axial movement between the core (2) and the sheath (3) and control the expansion of the weakened lateral area (5) of the sheath (3) transversely to the core (2).

11) A device as in claim 10, wherein the manipulation means (13) comprise rigid rods (14, 15) secured to the sheath (3) and the core (2) and capable of movement one relative to the other between an at rest configuration, in which the weakened lateral area (5) remains within the dimensional compass of the sheath considered transversely to the core (2), and an operating configuration in which the same weakened lateral area (5) is expanded transversely to the core (2) and beyond the dimensional compass of the sheath (3).

12) A method of implanting an endovascular stent (201) composed of two components (1P, 1S) in a vessel of the human or animal body exhibiting a main passage (203) and a collateral passage (203c) in order to dilate the vessel, comprising the steps of:

- inserting a first guide wire (G1) through the main passage (203) and beyond the point at which the branch into the collateral passage (203c) occurs;

- fitting a first component stent (1P) together with expansion means (304) to a catheter (300) affording two ducts (301, 302), with the component stent (1P) reduced to a configuration of minimal proportions and ensheathing expansion means folded and arranged in such a manner as to leave one end (302e) of the second duct (302) exposed;
- inserting the catheter (300) into the main passage (203) and advancing it along the guide wire (G1), inserted through the first duct (301), to the point at which the end (302e) of the second duct (302) is positioned opposite the collateral passage (203c);
- inserting a second guide wire (G2) through the second duct (302) of the catheter (300) and into the collateral passage (203c);
- operating the expansion means (304) in order to stabilize the first component stent (1P) within the main passage (203);
- withdrawing the catheter (300) from the relative passage (203) while keeping the second guide wire (G2) positioned in the collateral passage (203c);
- fitting the second component stent (1S) to the catheter (300) in the configuration of minimal proportions and advancing the catheter (300) along the second guide wire (G2) to the point of locating the second component stent (1S) in the collateral passage (203c);
- operating the expansion means (304) in order to stabilize the second component stent (1S) within the collateral passage (203c);

characterized

in that use is made of at least one guide wire (G1, G2) comprising a linear core (2), also a tubular sheath (3) associated coaxially with the core (2), rigidly associated with the core (2) at one end (4) and affording a weakened lateral area (5) capable of deforming elastically in response to the action produced by a relative axial movement between the core (2) and the sheath (3); and,

in that the step of advancing the catheter (300) along a guide wire (G1, G2) and into the relative passage (203, 203c) is preceded by a further step of inducing relative movement between the core (2) and sheath (3) of the guide wire (G1, G2), with the result that the weakened lateral area (5) of the sheath (3) is caused to expand transversely to the core (2) and interfere with the wall

of the passage (203, 203c), and the relative guide wire (G1, G2) thus stably anchored therein.

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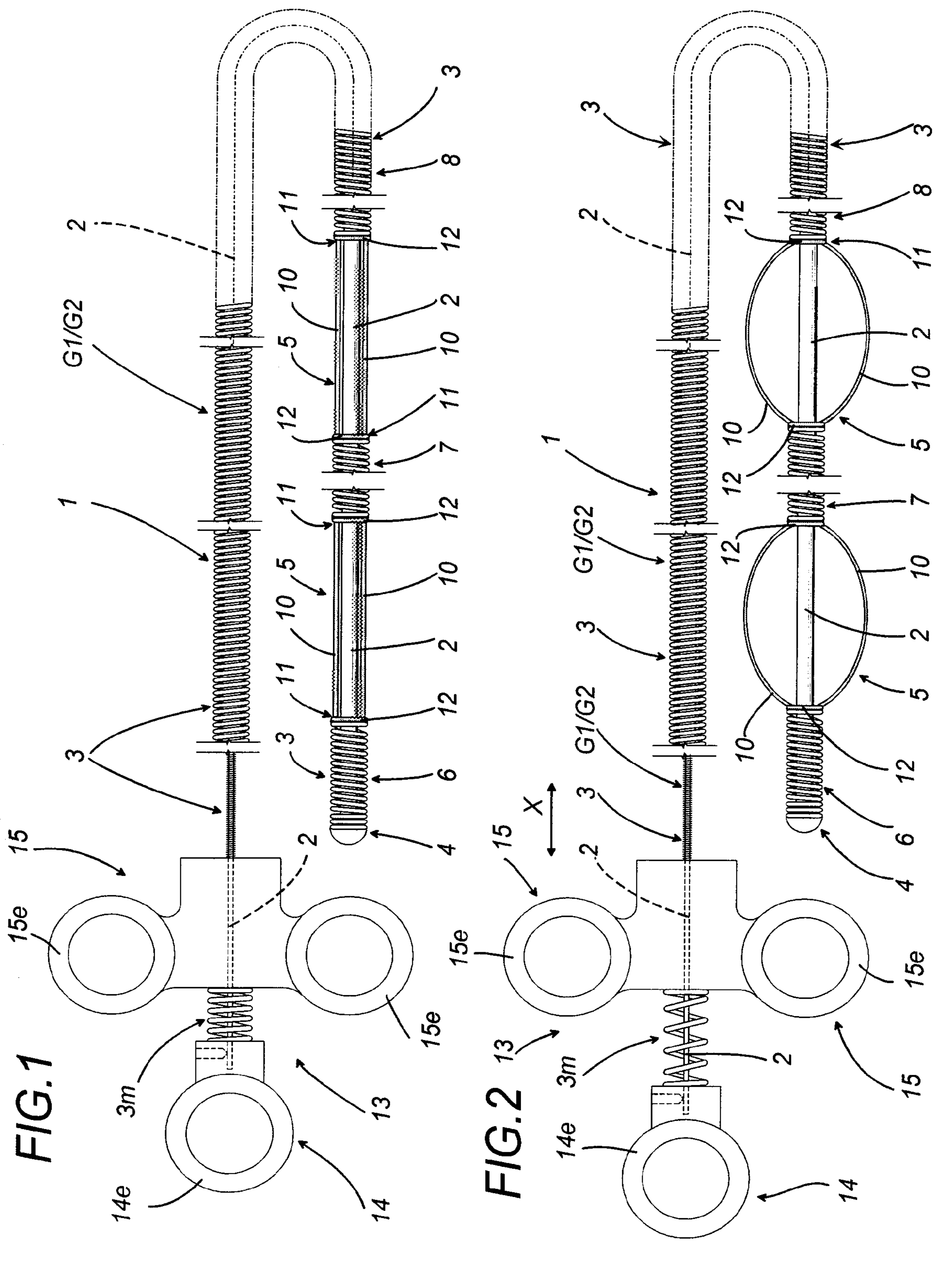


FIG.1

FIG.2

FIG.1a

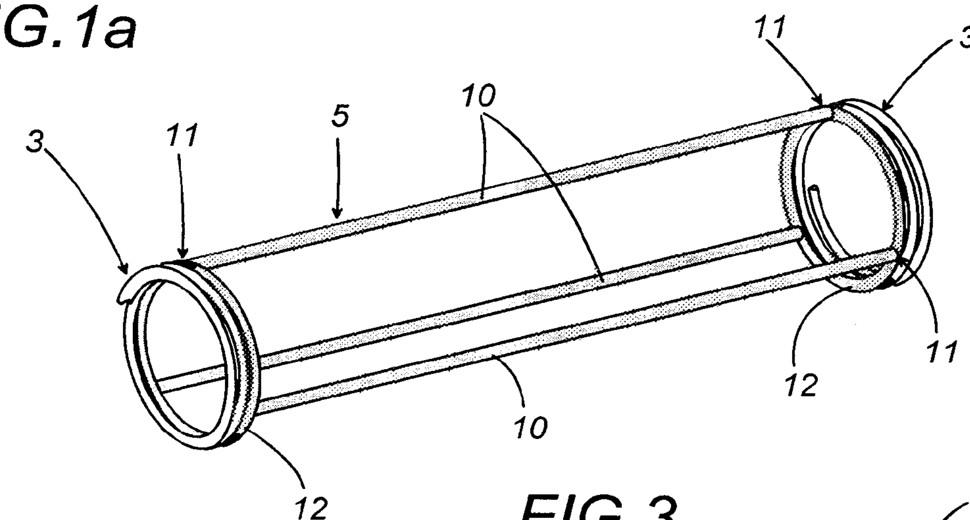


FIG.3

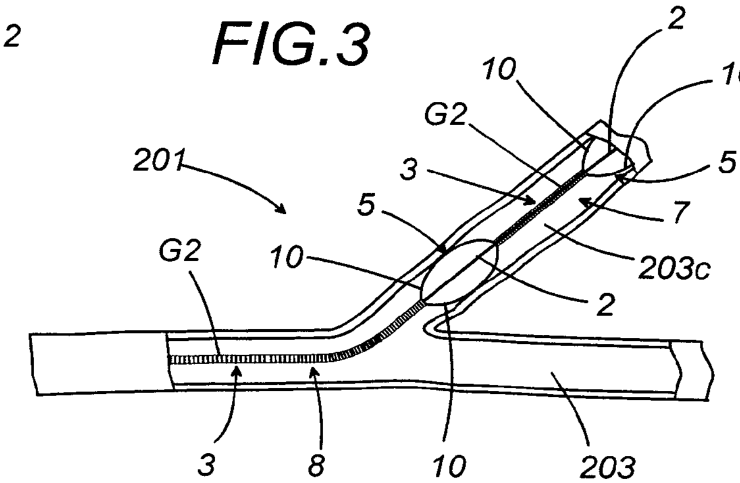


FIG.5

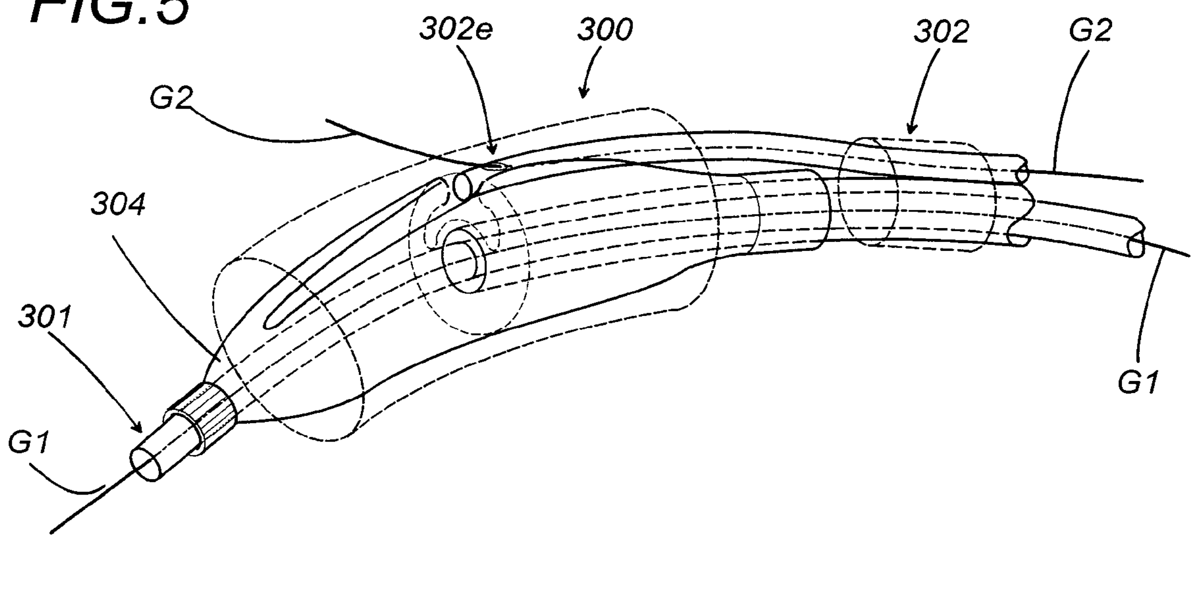


FIG.4a

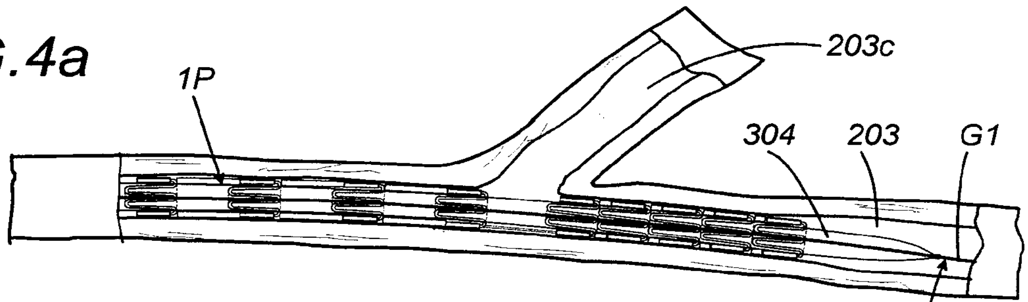


FIG.4b

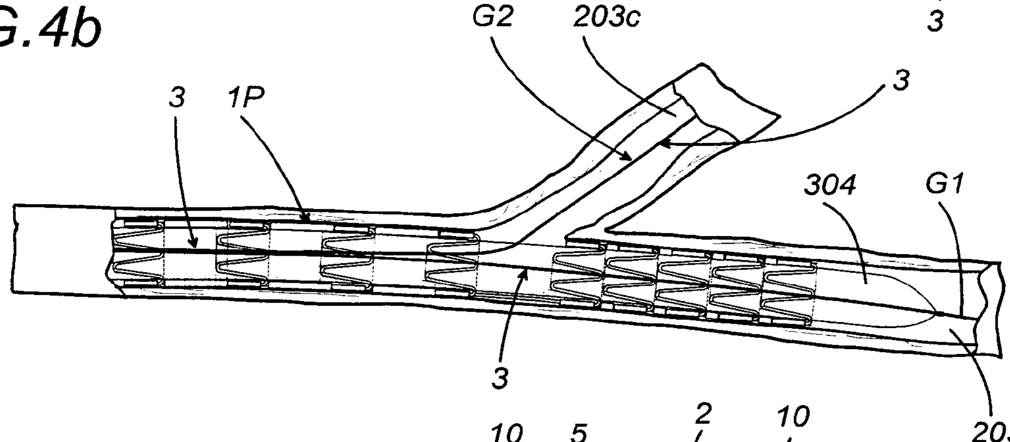


FIG.4b'

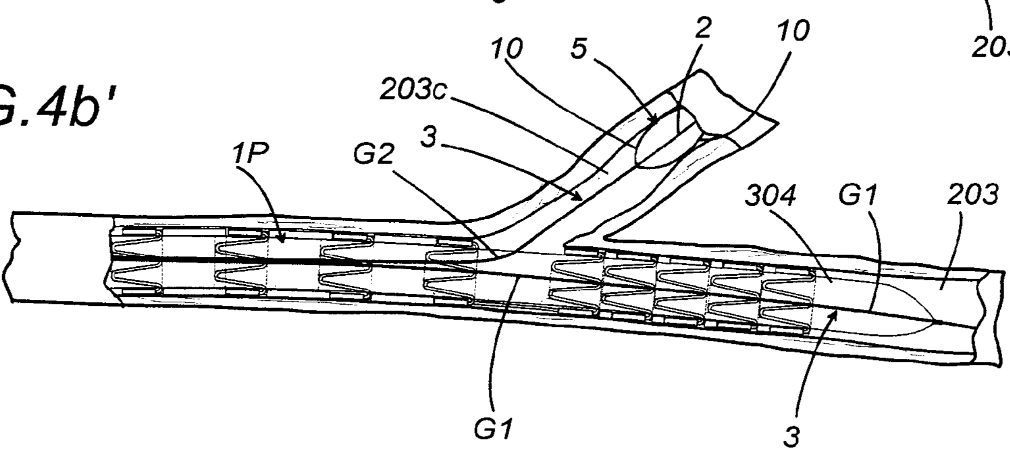


FIG.4c

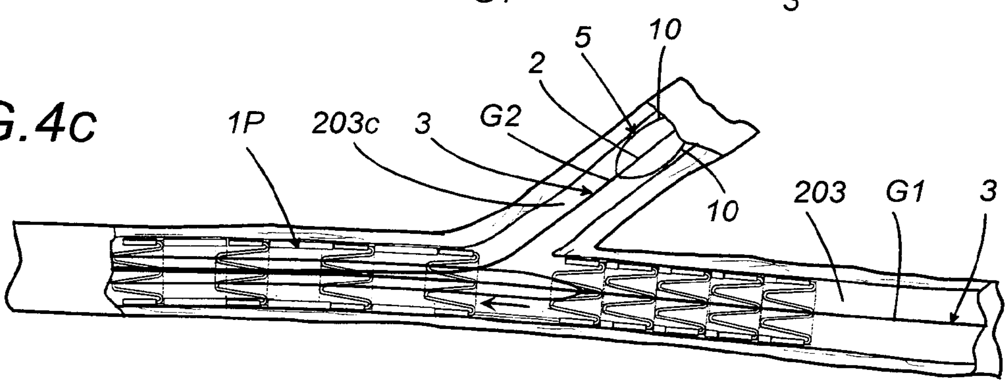


FIG.4d

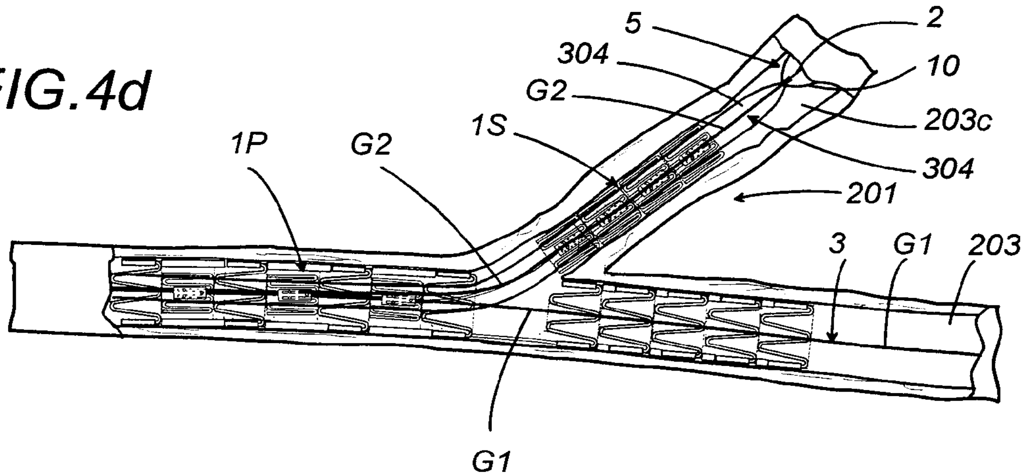
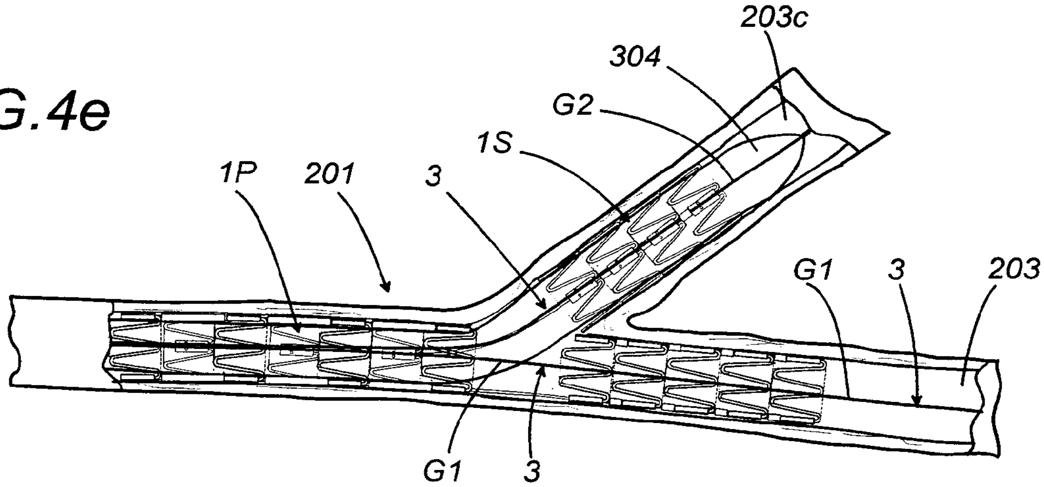

5
2
304
10
G2
203c
1S
304
1P
G2
201
3
G1
203
G1

FIG.4e


203c
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G2
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1P
201
3
G1
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G1
3

FIG.4f

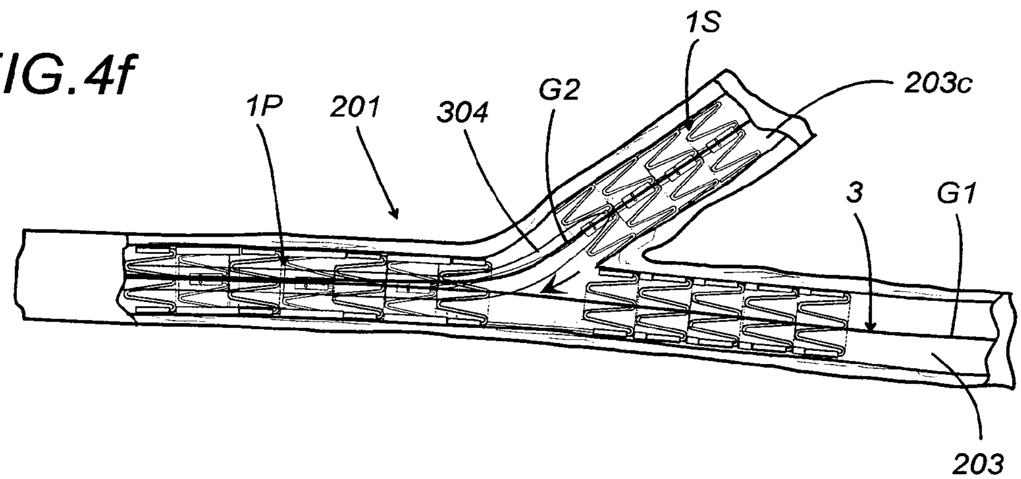
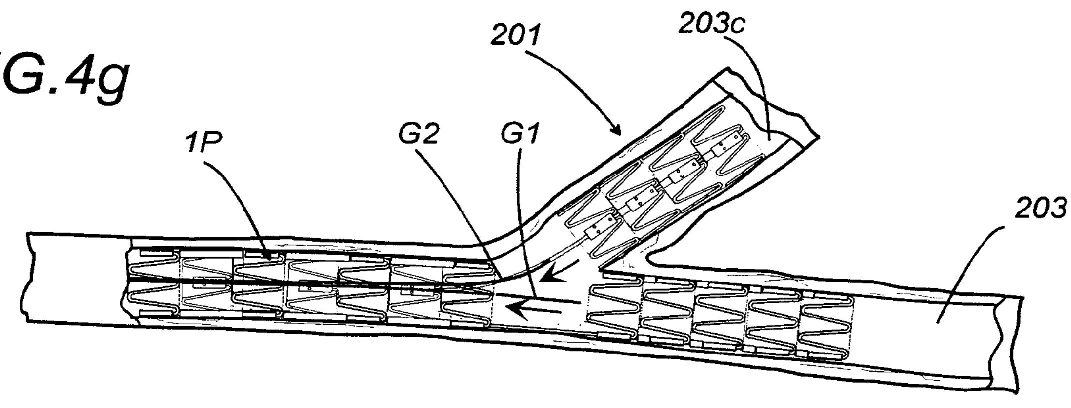


FIG.4g



INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 98/00617

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,Y	WO 97 45073 A (RICKARDS ANTHONY ;BARD GALWAY LIMITED (IE); BORGHI ENZO (IT)) 4 December 1997 see page 16, line 5 - page 18, line 10; figure 1 & ITBO960294 ---	1
Y A	EP 0 486 157 A (BARD INC C R) 20 May 1992 see the whole document ---	1 2,10
A	US 5 041 093 A (CHU MICHAEL S H) 20 August 1991 see abstract; figures ---	1,10
A	US 3 996 938 A (CLARK III WILLIAM T) 14 December 1976 see figures ---	1,10,11

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
13 July 1998	29.07.98

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 98/00617

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 91 02494 A (EVI CORP) 7 March 1991 see figure 1 -----	1,10

2

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB 98/00617

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 12
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inten nal Application No
PCT/IB 98/00617

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